In the United States Court of Federal Claims

No. 15-1207
Filed Under Seal: 19 June 2020
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NOT FOR PUBLICATION

R.S.,	*	
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Petitioner,	*	Vaccine Act; off-table case; influenza vaccine; Polyneuropathy, organomegaly, endocrinopathy, monoclonal gammopathy, and skin changes ("POEMS syndrome"); Guillain-Barré Syndrome ("GBS").
	*	
v.	*	
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

R.S., petitioner, *pro se*.

Linda S. Renzi, Senior Trial Attorney, Torts Branch, Civil Division, U.S. Department of Justice, with whom were *Joseph H. Hunt*, Assistant Attorney General, *C. Salvatore D'Alessio*, Acting Director, *Catherine E. Reeves*, Deputy Director, all of Washington, DC, for respondent.

OPINION AND ORDER

Petitioner R.S. ("petitioner") moved for review of Special Master Dorsey's decision that petitioner is not entitled to compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10, *et seq*. Petitioner claims she suffered Guillain-Barré Syndrome ("GBS") and, subsequently, polyneuropathy, organomegaly, endocrinopathy, monoclonal gammopathy, and skin changes ("POEMS" or "POEMS syndrome"), as a result of the influenza ("flu") vaccine she received on 1 October 2013. The Special Master denied compensation and found petitioner "failed to provide preponderant evidence that the flu vaccine . . . caused her injuries." *R.S. v. Sec'y of Health & Human Servs.*, No. 15-1207V, 2019 WL 7631017, at *1. (Fed. Cl. Spec. Mstr. Dec. 19, 2019).

I. Background

* This opinion was initially filed under seal pursuant to Vaccine Rule 18(b) of the Rules of the Court of Federal Claims. The Court provided the parties 14 days to propose redactions, if any, before the opinion was released for publication. Neither party proposed redactions. This opinion is now reissued for publication in its original form.

A brief recitation of the facts provides necessary context.[1]

A. Petitioner's Medical History and the Vaccination

Petitioner was born on 23 August 1972. *Id.* at *3. Before receiving the flu vaccination, petitioner did not have a history of neurological abnormalities, but had a history of cherry angiomas, basal cell neoplasms, and depression. *Id.*

Petitioner received the flu vaccine at issue on 1 October 2013. *Id.* "No adverse reaction was noted at the time of vaccine administration." *Id.* On 6 November 2013, petitioner was seen by Dr. Gopalan Umashanker, a neurologist at Cottage Hospital, when she "complained of weakness and numbness in her legs." *Id.* at *3. She reported to Dr. Umashanker that three days after her flu vaccination, "she experienced severe diarrhea and stomach pain." *R.S.*, 2019 WL 7631017, at *3. She also reported that around 10 October 2012, "she developed numbness in the tips of her toes, which eventually ascended to the pads of her feet and toes." *Id.* By the time she saw Dr. Umashanker, her symptoms progressed to include "pain in the calves and hips, fatigue, palpitations, numbness in the fingers, unsteady gait, and drooling." *Id.* "Dr. Umashanker assessed [petitioner] with 'probabl[e]' GBS due to the markedly diminished reflexes, sensory deficits, and facial involvement, though it was noted that additional testing would be needed to confirm the diagnosis." *Id.* (quoting Pet'r's Ex. 6, at 2). Petitioner "was admitted to Dartmouth Hitchcock Medical Center ("Dartmouth") that same day for further testing." *Id.*

At Dartmouth, petitioner "was seen by a second neurologist, Dr. Elijah Stommel," who "reviewed [petitioner's] history and opined that her course was 'concerning for acute inflammatory demyelinating polyneuropathy' or AIDP." *Id.* (quoting Pet'r's Ex. 7, at 6). A lumbar puncture "showed a slightly elevated protein of 57 (range: 15-45) with normal glucose." *R.S.*, 2019 WL 7631017, at *3. An electromyography ("EMG") "was consistent with a generalized peripheral neuropathy with demyelinating features." *Id.* Petitioner's "lab tests also indicated she had thrombocytosis, with an elevated platelet count of 473 x10(3)/mcL."[2] *Id.* Petitioner's discharge notes indicated a five-day course of intravenous immunoglobulin ("IVIG") treatment improved her extremity strength. *Id.* On 11 November 2013, she was discharged "with diagnoses of GBS and AIDP." *Id.*

From 26 to 29 November 2013, petitioner was hospitalized at Littleton Regional Healthcare ("Littleton Regional") "due to difficulties with her speech and gait." *Id.* at *4. She reported she experienced "increased tingling in the legs and fingers, difficulty walking, chest pain, and voice issues, roughly thirty-six hours prior to presentation." *R.S.*, 2019 WL 7631017, at *4. Petitioner's treating physicians "assessed her with a GBS flare and recommended further treatment with IVIG." *Id.* On 27 November 2013, "Dr. Stephen Goldberg conducted a serum protein electrophoresis ("SPEP") test without immunofixation ("IFE") to test for monoclonal gammopathy," a mandatory criterion for POEMS syndrome. *Id.* Petitioner "tested negative for the monoclonal protein," and "[t]he assessment remained GBS with treatment related

[1] As the basic facts in this case have not changed significantly since the Special Master's decision in this case, the Court's recitation of the background facts herein draws from that decision.

[2] Thrombocytosis is "[a]n increase in the number of platelets in the circulating blood." *Thrombocytosis*, Stedmans Medical Dictionary (Westlaw, last updated Nov. 2014).

fluctuation." *Id.* Discharge records indicated IVIG treatment improved petitioner's paresthesia[3] and gait. *Id.*

On 10 December 2013, petitioner was readmitted to Littleton Regional for persistent lower extremity weakness, sensory loss, paralysis in the lower extremities, paresthesia, gait abnormalities, and leg pain. *Id.* She received two infusions of IVIG treatment "with no improvement in strength." *R.S.*, 2019 WL 7631017, at *4. At this time, she was transferred back to Dartmouth to finish the five-day course of IVIG, which resulted in "a steady improvement in strength noted following her last treatment." *Id.*

On 20 December 2013, petitioner "presented for a follow-up appointment with Dr. Stommel" at Dartmouth. *Id.* "Dr. Stommel noted residual complaints, including sensory loss in the lower extremities, weakness in both legs, and subtle weakness in the biceps." *Id.* "A repeat nerve conduction study revealed a slight worsening in active denervation in the left tibialis." *Id.* "Given the progression of her symptoms, Dr. Stommel recommended that she continue IVIG treatments" and "prescribed Cellcept."[4] *Id.* Lab testing administered on 26 December 2013 and 15 January 2014 showed that petitioner's "thrombocytosis remained persistent with elevated platelet levels." *R.S.*, 2019 WL 7631017, at *4.

On 27 January 2014, petitioner was admitted to Littleton Regional for a fourth hospitalization. *Id.* She "complained of cognitive issues, fever, and chills" and indicated she "had 'trouble remembering things.'" *Id.* (quoting Pet'r's Ex. 5, at 64). She was diagnosed with "aseptic meningitis secondary to an IVIG treatment she received" on 23 January 2014. *Id.* "An MRI of the thoracic spine showed a spinal cord neoplasm at the T12-L1 level." *Id.* The neurologist "opined that the neoplasm was likely incidental and not related to petitioner's paresthesia, which he deemed to be related to a CIDP diagnosis." *Id.*

On 4 February 2014, "petitioner presented to the Massachusetts General Hospital ("MGH") neuromuscular clinic for an evaluation of her persistent symptoms." *R.S.*, 2019 WL 7631017, at *4. "Dr. Michael Bowley conducted a repeat EMG and nerve conduction analysis, both of which continued to show evidence of sensory and motor polyneuropathy." *Id.* "Dr. Bowley concluded that [petitioner] likely had CIDP, with multiple subsequent relapses." *Id.* Dr. Bowley considered petitioner's "'initial improvement' with IVIG . . . supportive of such a diagnosis; however, . . . her repeated relapses did not respond as well to further IVIG treatment."

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[3] Paresthesia is "[a] spontaneous abnormal usually nonpainful sensation (*e.g.*, burning, pricking); may be due to lesions of both the central and peripheral nervous systems." *Paresthesia*, Stedmans Medical Dictionary (Westlaw, last updated Nov. 2014).

[4] "Cellcept is the 'trademark for preparations of mycophenolate mofetil.'" *Miles v. Sec'y of Health & Human Servs.*, 142 Fed. Cl. 136, 141 n.19 (2018) (quoting *Dorland's Illustrated Medical Dictionary* 325 (32d ed. 2012)). Cellcept is an immunosuppressant "used with other medications to help prevent transplant organ rejection (attack of the transplanted organ by the immune system of the person receiving the organ) in people who have received kidney, heart, and liver transplants. . . . It works by weakening the body's immune system so it will not attack and reject the transplanted organ." *Lehner v. Sec'y of Health & Human Servs.*, No. 08-554V, 2015 WL 5443461, at *21 & n.53 (Fed. Cl. Spec. Mstr. July 22, 2015) (internal quotation marks omitted) (quoting U.S. National Library of Medicine, MedlinePlus, http://www.nlm.nih.gov/medlineplus/druginfo/meds/a601081.html (last visited July 9, 2015)).

Id. Petitioner's "platelet count remained elevated." *Id.* A 4 February 2014 SPEP test "was negative for monoclonal protein." *Id.*

On 12 February 2014, petitioner "was hospitalized for a thoracic laminectomy and mass resection . . . , both of which were unrelated to her underlying disease course." *R.S.*, 2019 WL 7631017, at *5. Before her surgery, petitioner's treating physicians discovered a spinal mass that pathologic testing confirmed was a T12 hemangioma. *Id.* at *5. On 18 February 2014, petitioner "was transferred to a rehabilitation facility for occupational and physical therapy." *Id.* She was discharged on 14 March 2014 with diagnoses including an "extradural spinal mass and post-T12 laminectomy, with a secondary diagnosis of GBS/CIDP." *Id.* Petitioner was seen by Dr. Jennifer Dineen for a follow-up appointment on 27 May 2014. *Id.* Petitioner "reported that she continued to experience fatigue, weakness in her legs, tremors, nerve pain, gait abnormalities, and blurry vision." *Id.* After her exam indicated "sensory and motor neuropathy with features indicative of a demyelinating polyneuropathy," Dr. Dineen recommended petitioner continue to take prescribed medication, but she "did not think further IVIG treatment would be helpful" to petitioner at that time. *R.S.*, 2019 WL 7631017, at *5.

Petitioner was seen at Littleton Regional on 14 July 2014 "with complaints of postural headaches, diplopia, incontinence, and cognitive issues." *Id.* "A lumbar puncture revealed an elevated opening pressure with no white blood cells detected, and a normal total protein at 38 mg/dl." *Id.* A brain MRI also returned normal results. *Id.* Petitioner was also seen by an ophthalmologist, Dr. Krista Haight, "for complaints associated with eye pressure, pain and hazy vision." *Id.* "Dr. Haight assessed petitioner with papilledema."[5] *Id.*

On 31 July 2014, petitioner was admitted to MGH for "complaints related to persistent headaches and vision changes." *R.S.*, 2019 WL 7631017, at *5. Dr. Mingming Ning, a neurologist, "suspected that [petitioner] might have POEMS syndrome and he recommended a hematology consult." *Id.* A 1 August 2014 SPEP test with immunofixation showed a "persistent IgA lambda monoclonal protein with components at 0.15 and 0.06 g/dl." *Id.*

When she returned to MGH on 12 August 2014, petitioner "complained of lethargy, reduced appetite, and blurry vision." *Id.* Dr. Annemarie Fogerty, the attending hematologist, "assessed petitioner with a progressive neuropathy, dual M-spike, and thrombocytosis, concerning for POEMS syndrome." *Id.* Dr. Fogerty noted "petitioner satisfied the two major criteria" for POEMS syndrome, neuropathy[6] and monoclonal gammopathy,[7] "as well as two minor criteria: papilledema and thrombocytosis." *Id.* On 14 August 2014, petitioner's vascular endothelial growth factor ("VEGF") levels were elevated at 1799 (reference range: 31-86), which confirmed her POEMS syndrome diagnosis. *R.S.*, 2019 WL 7631017, at *5. Petitioner

[5] Papilledema is "[e]dema of the optic disc, often due to increased intracranial pressure." *Papilledema*, Stedmans Medical Dictionary (Westlaw, last updated Nov. 2014).

[6] Neuropathy is "a disease involving the cranial nerves or the peripheral or autonomic nervous system." *Neuropathy*, Stedmans Medical Dictionary (Westlaw, last updated Nov. 2014).

[7] Monoclonal gammopathy is "any one of a group of disorders due to proliferation of a single clone of lymphoid or plasma cells and characterized by the presence of monoclonal immunoglobulin in serum or urine (visible on electrophoresis as a single peak)." *Monoclonal gammopathy*, Stedmans Medical Dictionary (Westlaw, last updated Nov. 2014).

was evaluated by another hematologist, Dr. Andrew Yee. *Id.* at *6. "Dr. Yee discussed POEMS syndrome with [petitioner] and explained her course in light of the accepted diagnostic criteria." *Id.* He opined "multiple clinical factors identified in [petitioner's] prior history, including: polyneuropathy, IgA lambda gammopathy, markedly elevated VEGF levels, thrombocytosis, and papilledema, supported a POEMS diagnosis." *Id.* Petitioner was discharged on 18 August 2014. *Id.*

On 29 January 2015, petitioner "underwent an autologous stem cell transplant," which improved her VEGF and platelet levels. *Id.*

On 17 June 2015, petitioner was seen by "Dr. Angela Dispenzieri, a hematologist at the Mayo Clinic, for a second opinion regarding [petitioner's] POEMS diagnosis." *R.S.*, 2019 WL 7631017, at *6. "Dr. Dispenzieri placed the onset of petitioner's illness in October 2013, when she experienced new onset fatigue and numbness/tingling in the feet, along with eruptions of cherry angiomas on the skin." *Id.* Dr. Dispenzieri noted that by October to November 2013, petitioner's symptoms progressed to include "muscle pain, difficulty walking, ascending hip pain, numbness in the fingers, and slight drooling," which initially improved with IVIG treatment. *Id.* Dr. Dispenzieri acknowledged additional treatment with IVIG through 2014 "did not result in similar levels of improvement," but "further treatment with cyclophosphamide mobilization, high-dose melphalan, and stem cell infusion resulted in good improvement." *Id.* Dr. Dispenzieri concluded this course was consistent with POEMS syndrome. *Id.*

"As of May 2015, [petitioner] continues to be treated for POEMS." *Id.* "She routinely experiences fatigue, intermittent headaches, hot flashes, foot swelling and discomfort, and diminished strength in both feet." *R.S.*, 2019 WL 7631017, at *6. Her gait has improved, and a 29 May 2015 neurological exam "showed normal function apart from marked weakness and sensory loss in the lower limbs." *Id.*

B. The Petition and Hearing Before the Special Master

Petitioner filed her vaccine petition against the Secretary of Health and Human Services ("respondent") on 15 October 2015. *See* Pet. for Vaccine Compensation, ECF No. 1. Petitioner requested compensation for GBS and POEMS syndrome she allegedly developed after receiving a flu vaccination on 1 October 2013. *See id.* at 1.

On 5 August 2016, petitioner filed the expert report of Dr. Norman Latov. *See* Pet'r's Ex. 29, ECF No. 26-1. Petitioner filed a supplemental medical expert report, also authored by Dr. Latov, on 27 March 2017. *See* Pet'r's Ex. 31. ECF No. 35-1. On 4 December 2017, petitioner filed a second supplemental expert report authored by Dr. Latov. *See* Pet'r's Ex. 38, ECF No. 54-1. On 11 October 2018, petitioner filed the expert report of Dr. Samir Parekh. *See* Pet'r's Ex. 57, ECF No. 75-1.

On 6 January 2017, respondent filed the expert report of Dr. Dennis Bourdette. *See* Resp't's Ex. A, ECF No. 33-1. On 16 June 2017, respondent filed the expert report of Dr. Brea Lipe. *See* Resp't's Ex. C, ECF No. 40-1. Respondent filed a supplemental expert report, also authored by Dr. Lipe, on 9 January 2019. *See* Resp't's Ex. E, ECF No. 101-1.

The Special Master held a two-day hearing on 29 and 30 January 2019 in Boston, Massachusetts. *See* Hr'g Tr., ECF Nos. 113–14. Petitioner and her husband testified, as well as petitioner's experts, Drs. Latov and Parekh. *See* Order at 1, ECF No. 104. Drs. Lipe and Bourdette testified on behalf of respondent. *See id.*

1. Witness Testimony

a. Fact Witnesses

i. Russell S., M.D.

Petitioner's husband, Dr. Russell S., began his testimony describing petitioner as "healthy" and "very physically active" before her vaccination. Hr'g Tr. at 141:21–22, ECF No. 113. Dr. S. recalled when petitioner returned from a work conference after receiving the flu vaccine, she began complaining that her feet were numb and felt pain in her calves. *Id.* at 145:8–22. Dr. S. noted that after petitioner initially sought treatment in November 2013, her symptoms began "rapidly progressing from a foot and ankle thing to essentially being paralyzed from the waist down and starting to complain of the lower part of her hands being numb and tingly," as well as drooling, heart palpitations, and difficulty breathing. *Id.* at 147:15–20. Dr. S. next recalled that petitioner's symptoms improved "immediately upon receiving the IVIG" treatment. *Id.* at 150:11–12. Dr. S. noted that upon discharge from Dartmouth, petitioner "still needed assistance standing" and "still had problems with balance," yet she returned home. *Id.* at 151:11–19. Dr. S. next recalled that about two weeks later petitioner was again hospitalized after a relapse in her symptoms but improved after additional rounds of IVIG treatment. *Id.* at 152:22–25, 153:3–4.

Dr. S. testified that after petitioner's third hospitalization, "there was hardly any change" with additional IVIG treatment, in contrast with the "noticeable change" petitioner experienced with the previous two infusions. Hr'g Tr. at 154:22–155:7. Dr. S. stated, "[a]t that point, we were told that it's not AIDP or [GBS] anymore, because she's had it for too long, so now the diagnosis was CIDP." *Id.* at 160:4–6.

Next, Dr. S. stated around April-May 2014, petitioner began complaining of angiomas, vision changes, head pain, and fatigue. *Id.* at 163:18–165:12. Dr. S. recalled that after an August 2014 hematologist consult, petitioner's POEMS syndrome diagnosis was confirmed through blood testing. *Id.* at 166:18–21. Dr. S. testified that petitioner continues to suffer from "a lot of ongoing physical disabilities," including fatigue, pain, and mental health issues. *Id.* at 172:6–19.

ii. R.S.

Petitioner similarly began her testimony by describing herself as healthy and physically active before receiving the vaccination. *Id.* at 184:18–19. Petitioner recalled about two weeks after the vaccination she began experiencing numbness and swelling in her feet and fatigue. Hr'g Tr. at 186:25–188:6. Petitioner testified that by early November 2013, her symptoms advanced to include gait abnormalities, pain, numbness in the fingers and legs, and drooling. *Id.*

at 188:7–189:20. After petitioner's first hospitalization, she had enough upper body strength to ambulate with a walker and spent the next couple of weeks at home until her second hospitalization. *Id.* at 192:1–14. Petitioner testified that she "was discharged remarkably better" after another round of IVIG treatment. *Id.* at 192:20–193:1. In the summer of 2014, petitioner began to experience cranial pressure and papilledema. *Id.* at 195:18–19, 196:8–11. Petitioner confirmed she was diagnosed with POEMS syndrome after VEGF levels were tested. *Id.* at 198:18–20.

Petitioner also recalled her visit with Dr. Dispenzieri, a POEMS syndrome expert, at the Mayo Clinic. Hr'g Tr. at 199:13–18. Petitioner did not remember having a comprehensive or detailed conversation of her medical history, but they had a good meeting and discussed a path forward. *Id.* at 199:21–25. Petitioner further explained her confusion when she reviewed Dr. Dispenzieri's visit notes, which she claims contained factual inaccuracies. *Id.* at 200:11–19. Lastly, petitioner testified that she continues to suffer POEMS-related symptoms, including depression and anxiety. *Id.* at 202:8–204:8.

b. Expert Witnesses

i. Petitioner's Expert Witness - Dr. Norman Latov, M.D.

Dr. Latov began his testimony by opining that petitioner was properly diagnosed with GBS at the outset of her injury. *Id.* at 12:17–13:22. Dr. Latov described GBS as "an acute or rapidly progressive neuropathy" and "[u]sually classically causing ascending weakness and sensory loss." *Id.* at 13:5–7. He also noted that GBS is "distinguished from other types of neuropathies by . . . EMG neuroconduction studies and . . . neural absence of spinal fluid, inflammatory changes and high CSF protein and responsive to treatment such as IVIG or plasmapheresis." Hr'g Tr. at 13:10–16.

Reviewing petitioner's medical history, Dr. Latov first noted that petitioner developed "symptoms of neuropathy," such as "parasthesias in her hands" and "progressive weakness" two weeks after her flu vaccine. *Id.* at 11:24–12:2. She also exhibited calf pain, ascending hip pain, numbness in the fingers, gait problems, and drooling, all of which Dr. Latov testified was consistent with a GBS diagnosis. *Id.* at 14:10–23. Based on his review of petitioner's medical records, Dr. Latov contended "she had a classical course" of GBS because "[s]he had the typical CSF spinal fluid findings and typical EMG neuroconduction studies and response to IVIGs, so she was a typical patient." *Id.* at 13:19–22. He also acknowledged that petitioner "had a rapid improvement in her strength" with IVIG treatment, which he claimed supports a GBS diagnosis in the early stages of petitioner's illness. *Id.* at 15:2–13.

Dr. Latov characterized petitioner's several relapses as "GBS with treatment-related fluctuations" and explained "the active period of disease could be six weeks or so, and the IVIG treatment may only work for a couple of weeks, so within the active period of illness, the patient may require repeat treatments if the initial treatments wore off." *Id.* at 20:13–17. Dr. Latov maintained petitioner's course fit this pattern because "each treatment seem[ed] to result in improvement for about two weeks, and then she would relapse." Hr'g Tr. at 20:20–22. Dr. Latov explained after petitioner's repeated relapses, her diagnosis "changed to chronic

inflammatory demyelinating neuropathy [("CIDP")], which is . . . chronic [GBS]." *Id.* at 22:5–10.

Dr. Latov then noted after being diagnosed with CIDP in December 2013, petitioner "presented with increasing intercranial pressure, and papilledema and was found to have high VEGF levels," which confirmed her POEMS syndrome diagnosis. *Id.* at 22:19–24. Dr. Latov described POEMS syndrome as "a slowly progressive neuropathy [that is] associated with a lambda monoclonal gammopathy, . . . high VEGF levels [and] does not respond well to IVIG or plasmapheresis." *Id.* at 23:12–15. He stated the diagnostic criteria for POEMS syndrome is "a combination of neuropathy, monoclonal gammopathy, or Castleman's disease and IVGF." *Id.* at 24:1–2.

Dr. Latov opined that GBS and POEMS syndrome are distinct diagnoses, positing that petitioner "had GBS which then evolved to CIDP, which is chronic GBS, and then she developed evidence of POEMS syndrome after that." *Id.* at 23:3–6. He also opined, "she probably had POEMS syndrome and CIDP concurrently until she developed more obvious manifestations of POEMS syndrome." Hr'g Tr. at 23:6–8. He noted, "many [POEMS] patients are diagnosed with CIDP first, and then later on, when they don't respond to IVIG or steroids, they re-evaluate diagnosis and they find that they have POEMS syndrome." *Id.* at 24:7–10. Despite the possibility for initial misdiagnosis, Dr. Latov maintained, "there was really no evidence for POEMS and the course was highly atypical for POEMS syndrome. . . . Although she subsequently did develop POEMS, at some point, . . . it certainly wasn't within . . . the initial . . . period of response to IVIG." *Id.* at 54:24–55:7. He also distinguished the polyneuropathy associated with POEMS syndrome from GBS-associated polyneuropathy by explaining the former is "chronic, not responsive to IVIG, [and] not associated with cranial nerve involvement." *Id.* at 24:13–14.

Dr. Latov next described a medical theory of "the mechanism by which a flu vaccination could cause autoimmunity[.]" *Id.* at 26:16–16. He explained, "something called molecular mimicry in the vaccine[] may recognize [or] structurally may have a similarity to the target organ and the immune system – the vaccinating agent turns against the body by mistake, because it's fooled into attacking itself." *Id.* at 26:17–22. He agreed that molecular mimicry is an accepted theory by which the flu vaccine causes GBS. *See* Hr'g Tr. at 27:8–22. He acknowledged, though, that there is no association between vaccination and POEMS. *Id.* at 55:13–57:2.

Dr. Latov recognized there is "no proof" that GBS/CIDP "contribute[] to the development of . . . POEMS syndrome." *Id.* at 30:4–7. He nonetheless maintained it is "more than a coincidence that [petitioner] developed monoclonal gammopathy and POEMS syndrome in the course of her illness as a consequence of the chronic immune stimulation." *Id.* at 30:7–10. Dr. Latov acknowledged there are no studies making a direct connection between GBS/CIDP and POEMS syndrome, and he instead relied upon individual case reports to causally connect GBS, CIDP, and POEMS syndrome. *Id.* at 40:3–10.

ii. Petitioner's Expert Witness - Dr. Samir Parekh, M.D.

Dr. Parekh, like Dr. Latov, opined that petitioner initially presented with GBS in November 2013 after receiving the flu vaccination, which subsequently caused petitioner to develop POEMS syndrome in August 2014. *Id.* at 225:16–21.

Dr. Parekh explained the "[t]wo main [diagnostic] criteria [of POEMS] are a monoclonal plasma cell disorder and neuropathy." Hr'g Tr. at 226:7–8. The other criteria are "a high vascular endothelial growth factor or Castleman's disease or sclerotic lesions," and the fourth criterion "can be one of many minor criteria such as organomegaly, endocrinopathy, skin changes, papilledema, thrombocytosis, and others." *Id.* at 226:8–10, 226:23–227:1. Addressing the diagnostic criteria, Dr. Parekh stated petitioner first developed polyneuropathy in 2013, then a monoclonal plasma cell disorder in 2014, and "she ultimately presented with raised intracranial tension and papilledema leading to the testing for [VEGF], which was elevated. And this all put together made the diagnosis of POEMS syndrome." *Id.* at 227:2–8. Dr. Parekh opined petitioner did not meet the diagnostic criteria for POEMS syndrome until August 2014. *Id.* at 250:7–10. He determined this date was the onset because "everything else can be hypothetical" and "[w]e need data to be able to diagnose something and treat it." *Id.* at 250:8–21.

Distinguishing petitioner's early symptoms from her later course, Dr. Parekh noted "petitioner's initial presentation was characterized by an ascending neurological deficit," which he considered "more characteristic of GBS than of POEMS syndrome." *Id.* at 246:25–247:5. While he knew of "anecdotal examples where POEMS may respond" to IVIG treatment, his preferred POEMS treatment is "directed at eradicating the plasma cell clone." Hr'g Tr. at 231:3–6. Further, Dr. Parekh testified that cranial nerve involvement, such as drooling, is atypical of POEMS syndrome, but otherwise deferred to "someone with Dr. Latov's experience" for assessment of neurological symptoms. *Id.* at 231:8–14. Dr. Parekh also acknowledged petitioner presented with thrombocytosis, in addition to neuropathies, in November 2013, but asserted the symptom "is a nonspecific finding" because it "has very many other causes" and "cannot be . . . specific enough for [POEMS] diagnosis." *Id.* at 244:18–246:18.

Dr. Parekh, like Dr. Latov, opined that "chronic immune stimulation leads to plasma cell dyscrasia," which he posits caused petitioner to develop POEMS syndrome, a form of plasma cell dyscrasia. *Id.* at 240:4–7; *see also id.* at 232:17–239:20. Dr. Parekh referenced two studies that he claimed support the association of monoclonal gammopathy and plasma cell disorders. *See id.* at 233:21–239:20. Dr. Parekh conceded, though, he was unaware of any medical literature or other evidence, apart from the Lindqvist article, directly connecting GBS as a precursor illness to POEMS syndrome. *Id.* at 251:19–252:6.

iii. Respondent's Expert Witness - Dr. Brea Lipe, M.D.

Dr. Lipe opined that petitioner "had POEMS from the outset of her symptoms," beginning in October-November 2013. Hr'g Tr. at 260:17–18. Addressing the onset of POEMS syndrome, Dr. Lipe referenced a study that found "85 percent of [POEMS] patients were initially misdiagnosed, and . . . the most common diagnosis initially [was] CIDP and AIDP." *Id.* at 261:6–9. Dr. Lipe explained "[t]he average amount of time it takes from the time a patient with POEMS presents with symptoms to the diagnosis is 9 to 16 months[,] [s]o it's typical that patients aren't diagnosed initially." *Id.* at 262:21–24. Dr. Lipe did not consider

petitioner's "presentation . . . atypical compared to the other patients with POEMS that [she has] ever had." *Id.* at 267:24–268:1. Indeed, Dr. Lipe testified she has "treated patients who [she] believes were initially misdiagnosed as having CIDP . . . . [a]nd then once [she] met them and ultimately diagnosed them with POEMS and treated their underlying plasma cell dyscrasia, they had improvement." *Id.* at 262:6–10. She was "not aware of any coexisting literature or evidence to suggest that you can have a distinct GBS and a distinct POEMS that are not related." *Id.* at 262:11–13.

Discussing the relevance of petitioner's thrombocytosis, Dr. Lipe agreed that thrombocytosis "generally is very nonspecific," but she nonetheless attributed petitioner's thrombocytosis in November 2013 and its persistence to POEMS syndrome. Hr'g Tr. at 266:2–8. Dr. Lipe explained, "transient or reactive-type thrombocytosis . . . would get better over time," but petitioner's "thrombocytosis never improved until she was started on definitive therapy against her plasma cell dyscrasia, at which time her thrombocytosis improved." *Id.* at 266:9–16.

Regarding petitioner's initial positive response to IVIG treatment, Dr. Lipe agreed "the majority of the literature suggests that patients with POEMS syndrome do not respond to IVIG." *Id.* at 264:13–15. She noted, however, "[t]here are case reports where patients do respond to IVIg, and in general we can use IVIg to treat neuropathies associated with plasma cell disorders." *Id.* at 264:15–18. In that vein, Dr. Lipe opined, "it's not irrelevant that [petitioner's] first admission was where she saw the bulk of her physical improvement and she got treated with steroids." *Id.* at 264:19–265:3. In support, Dr. Lipe referenced the Dispenzieri article, which reported that fifty percent of patients with POEMS syndrome respond to steroid therapy. *Id.* at 265:4–8; *see also* Resp't's Ex. C, at 2501.

Next, Dr. Lipe disagreed with petitioner's theory that chronic immune stimulation is "an accepted pathogenic mechanism for the development of plasma cell dyscrasias." Hr'g Tr. at 271:17–19. She testified she was unaware of any studies or case reports supporting petitioner's theory of causation. *Id.* at 272:12–19. Commenting on the article petitioner offered to support the theory, Dr. Lipe noted the report found only six out of 26,000 patients studied had monoclonal gammopathy of unknown significance with GBS. *Id.* at 275:22–276:3. Dr. Lipe therefore asserted, "to make a strong conclusion based on that is not something that I think anyone would suggest is evidence of pathogenesis." *Id.* at 276:4–6. To the contrary, Dr. Lipe testified, "we don't really know what causes POEMS." *Id.* at 290:4–5. Dr. Lipe explained that she knows "proinflammatory cytokines have a role in POEMS syndrome, but what they do in inflammatory diseases I can't say." *Id.* at 304:9–12.

iv. Respondent's Expert Witness – Dr. Dennis Bourdette, M.D.

Dr. Bourdette, like Dr. Lipe, opined that petitioner suffered from POEMS syndrome from the outset of her injury. Hr'g Tr. at 94:19–95:4. He also opined, "the flu vaccine did not play a role in her development of POEMS." *Id.* at 93:13–14.

Dr. Bourdette suggested, "the case needs to be put in the context of her ultimate diagnosis of POEMS." *Id.* at 94:19–21. Thus, "[l]ooking at [petitioner's medical history] through the lens

of that diagnosis," Dr. Bourdette was "convinced that the subacute inflammatory neuropathy that she experienced, which was diagnosed as idiopathic acute [GBS], was actually the first manifestation of her POEMS." *Id.* at 94:21–25. Additionally, Dr. Bourdette opined petitioner's "neuropathy in November of 2013 was actually caused by POEMS, which was not assessed for at the time because it's a rare presentation of a rare disease." *Id.* at 95:1–4. Dr. Bourdette observed, "there are case reports of patients who . . . either had established POEMS, or within a few weeks or months of a neuropathy clearly had POEMS that presented with subacute [GBS]-like neuropathy." *Id.* at 95:8–11. Dr. Bourdette disagreed with Dr. Latov's interpretation of those case reports, asserting that "there is a subacute presentation of a demyelinating neuropathy that is associated with POEMS," rather than GBS. Hr'g Tr. at 95:20–22. Dr. Bourdette also disagreed that petitioner "had acute [GBS] and that it evolved into CIDP." *Id.* at 95:22–24. He stated, "CIDP can present in a variety of ways including an initial episode that looks like [GBS] and patients can actually have a relapsing course of CIDP." *Id.* 95:24–96:2. Dr. Bourdette stated if petitioner "hadn't developed POEMS, [he] would have diagnosed her as having CIDP, not acute [GBS], but then followed by CIDP." *Id.* at 96:4–6.

Dr. Bourdette addressed the case report petitioner filed for the proposition that a POEMS syndrome patient can experience distinct GBS/CIDP prior to onset. *See id.* at 134:10–20. Contrary to Dr. Latov's interpretation, Dr. Bourdette asserted, "what they had diagnosed initially was [GBS] was actually a manifestation of the polyneuropathy of POEMS," and "that was part of the reason they reported the cases, to call this to the attention of people." *Id.* at 134:17–22.

Like Dr. Lipe, Dr. Bourdette also attributed petitioner's thrombocytosis in November 2013 to POEMS syndrome. Hr'g Tr. at 136:8–18. He testified thrombocytosis is "one of the minor symptoms of POEMS." *Id.* at 104:19. Dr. Bourdette observed, "if you look at the hematologists that ultimately diagnosed her with POEMS, one of the signs that they pointed to was persistent thrombocytosis," which "extended all the way back into November [2013] when she developed her neurological problem." *Id.* at 104:20–25. Dr. Bourdette also emphasized, "[i]t was not until [petitioner] was treated for POEMS that [her platelet levels] returned to normal." *Id.* at 104:15–16.

Addressing petitioner's response to IVIG treatment, Dr. Bourdette explained, "there are case reports where patients have had a subacute onset of their POEMS-related neuropathy, improving transiently with a course of IVIG," but he acknowledged, "it's well accepted that [IVIG] is not a good or effective treatment for treating fully-established POEMS." *Id.* at 97:12–16. Nevertheless, Dr. Bourdette did not consider "that that is a reason to say that she had [GBS] unrelated to as-yet-to-be-diagnosed POEMS syndrome." *Id.* at 97:18–21.

Dr. Bourdette also opined petitioner's medical theory of causation was "speculative." Hr'g Tr. at 108:14. Responding to Dr. Latov's theory, Dr. Bourdette stated Dr. Latov "acknowledge that [it had not] been established that vaccines could cause POEMS, and there weren't reports of that." *Id.* at 108:21–22. Further, Dr. Bourdette stated Dr. Latov "also acknowledged that vaccinations . . . had not been shown to cause a monoclonal gammopathy." *Id.* at 108:23–25. Dr. Bourdette, recalling Dr. Latov's testimony, stated "it would be a reportable first time, to report this series of events as a cause of POEMS. So I think that's an interesting speculation, but I think it's not well grounded in the medical literature." *Id.* at 108:25–109:4.

Dr. Bourdette was similarly unaware of any published articles supporting Dr. Latov's theory concerning the cause of POEMS because "[t]he cause of POEMS remains unknown." *Id.* at 138:3–4.

2. The Special Master's Decision Denying Compensation

On 19 December 2019, Special Master Dorsey issued her decision denying compensation because petitioner "failed to provide preponderant evidence that the flu vaccine she received on October 1, 2013, caused her injuries." *R.S.*, 2019 WL 7631017, at *1.

The Special Master began by stating "[a]lthough the parties agree that petitioner was appropriately diagnosed with POEMS syndrome, they firmly dispute the onset of the condition, as well as the appropriate diagnosis for her neuropathy-related symptoms in October and November 2013." *Id.* at *29. Although "[b]oth sides devoted time at hearing to addressing whether vaccine-induced GBS could be shown to cause POEMS syndrome," the Special Master indicated, "[t]he medical records in this case, however, suggest a more pertinent question: whether petitioner GBS at all." *Id.* She reasoned, "[t]he medical theory of causation proffered by petitioner hinges on the undersigned finding that her neuropathy-related symptoms in October and November 2013 are attributable to a GBS diagnosis, not POEMS. Therefore, if petitioner did not suffer from GBS at the outset, then her claim cannot succeed." *Id.*

The Special Master first considered "whether [petitioner] has established, by a preponderance of the evidence, that she suffered from GBS as a precursor illness to her later-diagnosed POEMS syndrome." *Id.* The Special Master noted, "[a]s Federal Circuit precedent establishes, in certain cases it is appropriate to determine the nature of a petitioner's injury before engaging in the *Althen* analysis." *Id.* (citing *Broekelschen v. Sec'y of Dept. of Health & Human Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010)). The Special Master stated, "[i]t is indisputable that petitioner's treaters considered both GBS and CIDP diagnoses over the course of her illness and followed the appropriate treatment protocol for both diseases." *R.S.*, 2019 WL 7631017, at *29. Weighing the record evidence, the Special Master determined "[a]lthough there is earlier-in-time evidence in the medical records interpreting petitioner's course as GBS, and CIDP thereafter, those records by themselves, viewed in retrospect, suggest that petitioner more likely than not suffered from POEMS syndrome at the outset, rather than GBS or CIDP." *Id.* In support, the Special Master explained that petitioner's "symptoms remained persistent through 2014, despite receiving treatment for presumed GBS and later CIDP, a fact that Dr. Lipe relied upon in opining that petitioner likely had POEMS syndrome from the early stages." *Id.* The Special Master similarly reasoned that "laboratory testing, followed by an alteration of petitioner's treatment, also strongly supports the POEMS diagnosis." *Id.*

Addressing petitioner's preferred diagnosis, the Special Master stated petitioner's "experts seemingly posit that greater weight should be given to the views of her early-in-time treating physicians who made the initial GBS/CIDP diagnoses, despite the fact that petitioner's later-in-time treatment evaluations took into account her persistent and evolving symptoms." *Id.* at *30. Similarly, the Special Master noted, "[t]here is no evidence in the record suggesting that any other treating physicians who saw petitioner *after* the POEMS diagnosis was established

disagreed with the conclusions regarding her ultimate diagnosis, or posited that any precursor illness, like GBS, was appropriate." *Id.*

The Special Master found "Dr. Lipe's interpretation of the above-referenced records regarding disease onset and progression was ultimately more persuasive." *R.S.*, 2019 WL 7631017, at *30. The Special Master emphasized, "Dr. Lipe based her opinion on a complete review of the record in light of petitioner's entire course." *Id.* For example, "[h]aving treated multiple POEMS patients, she observed that a patient may experience neuropathy-related symptoms long before they are actually diagnosed with POEMS and even before such a diagnosis might be proper based on the diagnostic criteria." *Id.*

The Special Master also considered Dr. Lipe's testimony "more persuasive in identifying inconsistencies in petitioner's history that prolonged the initial POEMS syndrome diagnosis." *Id.* For example, Dr. Lipe's "reading of petitioner's contemporaneous SPEP test results, . . . pointed out that early symptoms and testing actually supported a suspicion for a POEMS diagnosis prior to the date documented in the record." *Id.*

In contrast, "petitioner's experts failed to establish a reasonable explanation for petitioner's course in light of her complete medical history." *Id.* Further, "Drs. Latov and Parekh generally found more significant the initial GBS/CIDP diagnoses and the IVIG treatment she received thereafter without explaining the subsequent changes in her course and overall improvement following treatment for POEMS syndrome." *R.S.*, 2019 WL 7631017, at *30.

The Special Master accordingly determined Dr. Lipe "convincingly offered an interpretation of the medical history that petitioner has not rebutted. It is thus improbable that petitioner suffered from distinct GBS as a precursor illness to her later-diagnosed POEMS syndrome." *Id.* at *31.

Next, applying the three-pronged test for causation the Federal Circuit articulated in *Althen*, the Special Master asserted, "[the] conclusion that petitioner likely did not suffer from GBS at the outset of her illness largely moots petitioner's arguments that the flu vaccine played any role in her development of POEMS syndrome thereafter, given that petitioner's theory requires a finding that she experienced vaccine-induced GBS." *Id.* The Special Master nonetheless "consider[ed] the evidence offered by petitioner in support of the first *Althen* prong under the assumption that petitioner offered preponderant evidence in support of a GBS diagnosis." *Id.*

Analyzing the first prong, the Special Master observed, "[t]he molecular mimicry theory has been accepted in the Vaccine Program as a reliable explanation for how the flu vaccine can initiate an autoimmune process resulting in GBS." *Id.* at *32. The Special Master noted, "Drs. Latov and Parekh propose that the chronic stimulation of B-cells can cause the body to produce an abundance of plasma cells," but indicated "[t]he medical articles offered in support, however, do not support this assertion." *Id.* Moreover, "[p]etitioner's expert, Dr. Latov, even acknowledged at hearing that petitioner's case would be the first reported instance of POEMS syndrome occurring as a direct result of GBS/CIDP via the mechanism posited herein." *R.S.*,

2019 WL 7631017, at *32. The Special Master therefore determined "[s]uch a novel theory, without more persuasive scientific evidence, does not rise to the level of sound and reliable." *Id.*

The Special Master similarly found petitioner failed to satisfy the second *Althen* prong because "[w]ithout being able to establish a reliable medical theory, or that she suffered from GBS, petitioner cannot show that the vaccine more likely than not caused her illness thereafter." *Id.* at *33. The Special Master stressed that "[f]ollowing her diagnosis with POEMS, no treaters appear to have embraced an association between the flu vaccine and petitioner's subsequent development of POEMS." *Id.* at *33.

Lastly, analyzing the third *Althen* prong, the Special Master suggested "[t]here is support in the relevant medical literature for the conclusion that the timeframe between vaccination and petitioner's subsequent symptoms was medically acceptable—assuming she suffered from GBS as she alleges." *Id.* The Special Master determined, however, "petitioner has not established that she more likely than not suffered from GBS at the outset of her illness." *Id.* at *34. Lastly, the Special Master reasoned, "even if petitioner had accepted the conclusion that her symptoms in October and November 2013 were indicative of POEMS, and argued that it was caused by her receipt of the flu vaccine, there would still be a lack of medically-acceptable temporal relationship, due to the fact that neither Dr. Latov nor Dr. Parekh proposed that vaccinations could cause POEMS syndrome at all let alone offered some medically cognizable timeframe for such an injury." *R.S.*, 2019 WL 7631017, at *34.

For these reasons, the Special Master determined petitioner did not establish causation and accordingly was not entitled to compensation under the Vaccine Program. *Id.*

3. Petitioner's Motion for Review

On 21 January 2020, petitioner filed her *pro se* motion for review.[8] *See* Pet'r's Mot. for Review, ECF No. 144. The filing contains: (1) an incomplete, two-page outline of a formal brief moving for review of the Special Master's decision with a handwritten note, stating "please see attached document;" (2) an attached memorandum listing 11 bullet points detailing factual disagreements with the Special Master's decision; and (3) an addendum to the memorandum with fourteen additional factual disagreements with citations to the Special Master's decision. *See id.* The factual disagreements focus on petitioner's fundamental challenge to the Special Master's holding that petitioner did not prove by preponderant evidence that petitioner had GBS. *See generally id.* at 3–8. Petitioner argues although "[t]he Special Master concluded that [petitioner] never had GBS, a diagnosis in the Vaccine Injury table[,] . . . all of her care providers and the preponderance of evidence suggests otherwise." *Id.* at 3. Concerning the medical theory of causation, petitioner recognizes "[t]he possible association between GBS and POEMS was less clear," but because the cause of POEMS is unknown, she posits, "[i]t seems therefore more than coincidental that a previously healthy 41 year old woman would develop POEMS after GBS after a flu vaccine." *Id.*

[8] Petitioner was previously represented by counsel throughout the proceedings before the Special Master, but on 13 January 2020, petitioner's counsel moved to withdraw as attorney of record. *See* Mot. to Withdraw as Att'y of R., ECF No. 141. The Special Master granted the motion to withdraw on 22 January 2020, and petitioner proceeded representing herself. *See* Order, ECF No. 145.

On 18 February 2020, respondent filed its response to petitioner's motion for review. *See* Resp't's Resp. to Pet'r's Mot. for Review, ECF No. 153. Respondent argues "[p]etitioner does not assert that the special master's findings were arbitrary or capricious. . . . [S]he simply details her disagreements with particular findings of fact made by the special master, and requests that this Court reconsider specific evidence already considered by the special master, but reach a different conclusion." *Id.* at 14. Pointing to Dr. Bourdette's and Dr. Lipe's testimony, respondent contends "the special master correctly concluded that respondent's experts were more persuasive, in large part because their opinions were based on the medical records in their entirety, considering petitioner's final diagnosis of POEMS and working backwards, as opposed to petitioner's experts, who considered petitioner's initial diagnosis of GBS and later diagnosis of POEMS as isolated events." *Id.* at 15. Additionally, respondent argues "[p]etitioner does not appear to assert that the special master erred in reaching her conclusion that petitioner had not established that GBS can cause POEMS syndrome, but again improperly requests that this Court reach a different conclusion, based on the same evidence considered by the special master." *Id.* at 18. Respondent emphasizes Dr. Latov's testimony "acknowledging that petitioner's case would be the first instance of POEMS syndrome occurring as a direct result of GBS/CIDP via the mechanism he posited . . . [which] support[s] the special master's determination that petitioner failed to demonstrate a logical sequence of cause and effect." *Id.* at 19. Lastly, respondent maintains "without the ability to establish a reliable medical theory, or that she actually suffered from GBS, petitioner could not show that her flu vaccination more likely than not caused her POEMS syndrome." *Id.*

III. Discussion

A. Legal Standards

i. The Court's Standard of Review of a Special Master's Decision

The Vaccine Act provides this Court jurisdiction to review a Special Master's decision upon timely motion of either party. *See* 42 U.S.C. § 300aa-12(e)(1)–(2). In reviewing the record of the proceedings before the Special Master, the Court may: (1) "uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision;" (2) "set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law;" or (3) "remand the petition to the special master for further action in accordance with the court's direction." *Id.* § 300aa-12(e)(2). "Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the 'not in accordance with law' standard; and discretionary rulings under the abuse of discretion standard." *Saunders v. Sec'y of Dept. of Health & Human Servs.*, 25 F.3d 1031, 1033 (Fed. Cir. 1994) (quoting *Munn v. Sec'y of Dept. of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992)).

It is not the Court's role "to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence." *Lampe v. Sec'y of Dept. of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (quoting *Munn*, 970 F.2d at 871)). The Court also does

"not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder." *Id.* (quoting *Munn,* 970 F.2d at 871). "Reversal is appropriate only when the special master's decision is arbitrary, capricious, an abuse of discretion, or not in accordance with the law." *Snyder ex rel. Snyder v. Sec'y of Dept. of Health & Human Servs.*, 88 Fed. Cl. 706, 718 (2009). The arbitrary and capricious standard is a "highly deferential standard of review:" "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines ex rel. Sevier v. Sec'y of Dept. of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991).

ii. The Standard of Causation in Vaccine Cases

"A petitioner seeking compensation under the Vaccine Act must prove by a preponderance of the evidence that the injury or death at issue was caused by a vaccine." *Broekelschen v. Sec'y of Dept. of Health & Human Servs.*, 618 F.3d 1339, 1341 (Fed. Cir. 2010) (citing 42 U.S.C. §§ 300aa-11(c)(1)). "A petitioner can show causation under the Vaccine Act in one of two ways:" (1) "by showing that she sustained an injury in association with a vaccine listed in the Vaccine Injury Table," in which case "causation is presumed;" or (2) "if the complained-of injury is not listed in the Vaccine Injury Table . . . the petitioner may seek compensation by proving causation in fact." *Id.* at 1341–42 (internal citations omitted). Vaccine cases employ a burden shifting standard: "[o]nce the petitioner has demonstrated causation, she is entitled to compensation unless the government can show by a preponderance of the evidence that the injury is due to factors unrelated to the vaccine." *Id.* at 1342 (citing *Doe v. Sec'y of Dept. of Health & Human Servs.*, 601 F.3d 1349, 1351 (Fed. Cir. 2010); 42 U.S.C. § 300aa-13(a)(1)(B)).

"When a petitioner has suffered an off-Table injury, as is the case here, [the Federal Circuit] has established the following test for showing causation in fact under the Vaccine Act:"

> [The petitioner's] burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. at 1345 (quoting *Althen v. Sec'y of Dept. of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)). Under the first prong, "[a] petitioner must provide a 'reputable medical or scientific explanation' for its theory." *Boatmon v. Sec'y of Dept. of Health & Human Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting *Moberly ex rel. Moberly v. Sec'y of Dept. of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010)). "While it does not require medical or scientific certainty, it must still be 'sound and reliable.'" *Id.* (quoting *Knudsen ex rel. Knudsen v. Sec'y of Dept. of Health & Human Servs.*, 35 F.3d 543, 548–49 (Fed. Cir. 1994)). Petitioners "need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act." *Andreu ex rel. Andreu v. Sec'y of Dept. of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009). Where such evidence is introduced, however, it must not be viewed "through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's

preponderant evidence standard." *Id.* at 1380. To demonstrate a logical sequence, "medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Capizzano v. Sec'y of Dept. of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006) (quoting *Althen*, 418 F.3d at 1280). Lastly, "the proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Dept. of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

iii. *Pro Se* Litigants

A *pro se* plaintiff's pleadings are held to "less stringent standards than formal pleadings drafted by lawyers." *Haines v. Kerner*, 404 U.S. 519, 520–21 (1972). Nonetheless, courts have long recognized "[a]lthough *pro se* plaintiffs are given some leniency in presenting their case, their *pro se* status does not immunize them from pleading facts upon which a valid claim can rest." *Hutchens v. United States*, 89 Fed. Cl. 553, 560 (2009). If a petitioner acts *pro se* in the drafting of her pleading it "may explain its ambiguities, but it does not excuse its failures, if such there be." *Henke v. United States*, 60 F.3d 795, 799 (Fed. Cir. 1995).

B. Analysis

Petitioner argues the Special Master erred in concluding petitioner did not establish she suffered from GBS, and in doing so, the Special Master "chose to believe the speculative claims of one government witness over the clear evidence in the medical records and over the expertise of 5 neurologists." Pet'r's Mot. for Review at 3. While petitioner acknowledges "[t]he possible association between GBS and POEMS [is] less clear, as there is only one report in the medical literature (from Poland) linking the two," petitioner asserts her witnesses "described a plausible biologic mechanism by which the chronic stimulation of plasma cells from GBS could, in theory, precipitate the formation of a plasma cell neoplasm." *Id.* Since "[t]here is no other known etiology for POEMS," petitioner argues "the experts' theory is at least as plausible as any." *Id.*

Petitioner lists eleven disagreements with the Special Master's factual findings:

> 1) POEMS is not an illness of acute onset as occurred in [petitioner's] case.
> 2) POEMS causes weakness but generally not paralysis and certainly not within the course of hours as GBS typically does.
> 3) The neuropathy of POEMS does not typically follow an ascending pattern as [petitioner] had and as is typical of GBS.
> 4) There are anecdotal reports of POEMS patients responding to treatment with IVIG. Typically they do not . . . . In the rare patient with POEMS who might respond, it would be expected that the response would be maintained. [Petitioner] responded dramatically well to her first two courses of IVIG and then upon her third episode of neuropathy, her response was minimal to nil. . . .
> 5) [Petitioner's] initial SPEP was normal. . . . [I]t more likely would have been negative as she had GBS . . . .

> 6) [Petitioner's] several initial EMG studies showed preservation of the sural nerve. This is typical and expected in GBS. . . . On a subsequent EMG at MGH (Dr. Chad), she "lost" her sural nerve. While not much was made of this at the time, I believe it is a very critical finding to suggest that what started as GBS became something else.
> 7) [Petitioner's] most prominent and dangerous symptoms of POEMS – increased intracranial pressure with visual impairment and profound weight loss – were not present early on in the course of her disease. These are not seen with GBS but are seen with POEMS Syndrome.
> 8) [Petitioner's] thrombocytosis was argued to be a sign that she had POEMS from the start by Dr. Lipe. Thrombocytosis is associated with POEMS but is also a common acute phase reactant. . . . [I]t was not until 8/14 that the ongoing presence of [the high platelet count] (in the absence of further acute medical events) triggered a Hematology consult at MGH which led to the discovery of POEMS. However that does not mean she had POEMS all along.
> 9) 50% of GBS patients have pain. . . . The argument that pain suggests against the initial diagnosis of GBS is in error . . . .
> 10) Swallowing can be affected by GBS. . . .
> 11) Hemangiomas were present early in her disease, in fact even before her initial illness. GLOMERULOID hemangiomas are specific to POEMS Syndrome. [Petitioner] had a Dermatologist remove one and it was the sporadic type, not the glomeruloid type. . . . [T]he early presence of hemangiomas . . . are not indicative of her having had POEMS earlier than when her POEMS diagnosis was made.

Id. at 3–4.

Respondent counters, arguing, "petitioner does not assert that the special master's findings were arbitrary or capricious. On review, she simply details disagreements with particular findings of fact made by the special master, and requests that this Court reconsider specific evidence already considered by the special master, but reach a different conclusion." Resp't's Resp. to Pet'r's Mot. for Review at 14. Respondent first acknowledges petitioner's "theory of causation hinges on the premise that she suffered from vaccine-related GBS/CIDP that caused her to develop POEMS syndrome," and argues "[t]he special master properly held that petitioner was not entitled to compensation primarily because she failed to establish by preponderant evidence that she suffered from GBS." *Id.* The Special Master, according to respondent, "correctly concluded that respondent's experts were more persuasive, in large part because their opinions were based on the medical records in their entirety, considering petitioner's final diagnosis of POEMS and working backwards, as opposed to petitioner's experts, who considered petitioner's initial diagnosis of GBS and later diagnosis of POEMS as isolated events." *Id.* at 15. Respondent also argues "[p]etitioner does not appear to assert that the special master erred in reaching her conclusion that petitioner had not established that GBS can cause POEMS syndrome, but again improperly requests that this Court reach a different conclusion, based on the same evidence considered by the special master." *Id.* at 18. Respondent maintains the Special Master's "decision carefully considered the literature relied upon by petitioner's experts to support their theory and concluded that none [of] the articles offered by petitioner's experts associate chronic immune stimulation pathologically with the

onset of POEMS." *Id.* at 19. Accordingly, respondent argues "without the ability to establish a reliable medical theory, . . . petitioner could not show that her flu vaccination more likely than not caused her POEMS syndrome." *Id.*

1. Whether the Special Master's Finding that Petitioner Suffered From POEMS From the Outset of Her Injury Was Arbitrary or Capricious

Petitioner first challenges the Special Master's finding that petitioner suffered from POEMS—not GBS—from the outset of her injury in late 2013. Petitioner argues, "all of her care providers and the preponderance of evidence suggests otherwise." Pet'r's Mot. for Review at 3. In addition, "[t]he Special Master chose to believe the speculative claims of one government witness over the clear evidence in the medical records and over the expertise of 5 Neurologists . . . ." *Id.* Respondent argues, on the other hand, "the special master offered entirely rational reasons for finding the testimony of respondent's experts more persuasive on the issue of whether petitioner suffered from GBS." Resp't's Resp. to Pet'r's Mot. for Review at 18.

The experts agreed petitioner suffers from POEMS syndrome, but they disagreed whether petitioner suffered from GBS as a precursor condition that then caused petitioner's POEMS syndrome. During the hearing, Dr. Latov opined petitioner "had GBS which then evolved to CIDP, . . . [a]nd she probably had POEMS syndrome and CIDP concurrently until she developed more obvious manifestations of POEMS syndrome." Hr'g Tr. at 23:4–8. Dr. Latov maintained that petitioner's early symptoms could not be attributed to her later-diagnosed POEMS syndrome; rather, he opined they were two separate disease courses. *See id.* at 42:20–24; 55:4–7 ("Although she subsequently did develop POEMS, at some point, and we don't know exactly when, but it certainly wasn't within the . . . period of response to IVIG."). Dr. Latov explained IVIG treatment is beneficial to patients with CIDP-associated monoclonal gammopathy, but not POEMS-associated monoclonal gammopathy; this led him to opine petitioner's initial improvement with IVIG treatment was indicative of GBS in contrast with her later worsening condition that did not respond to IVIG treatment. *See id.* at 37:17–38:8, 54:23–55:8. Dr. Latov similarly distinguished petitioner's early neuropathy from her later POEMS syndrome symptoms to suggest petitioner initially had GBS because her initial disease onset was acute, unlike POEMS, which "comes on very slowly." *Id.* at 55:14–16; *see also id.* at 57:12–16 ("I think they're distinct, again, because of the rapid onset and response to treatment which usually when POEMS responds to treatment, . . . it takes months before the neuropathy starts getting better."). Dr. Parekh similarly opined petitioner's "initial presentation was characterized by an ascending neurological deficit," which he contended "is more characteristic of GBS than of POEMS syndrome." *Id.* at 246:25–247:2. Further, although Dr. Parekh acknowledged petitioner's platelet levels returned to normal once she was treated for POEMS syndrome and thrombocytosis is a minor criteria for POEMS, he nonetheless considered petitioner's thrombocytosis a "nonspecific finding" because "it can happen from very many causes." *Id.* at 245:15–246:16.

Dr. Lipe, in contrast, presented a more inclusive assessment of petitioner's condition, opining that petitioner "had POEMS from the outset of her symptoms." Hr'g Tr. at 260:17–18. First, Dr. Lipe stated, "[m]ost of the reports that we have of POEMS syndrome and any patient studies that we have suggest that patients are initially misdiagnosed, and the primary

misdiagnosis is either CIDP or AIDP," but "they are ultimately diagnosed with POEMS," which she suggests "happened in this case." *Id.* at 260:18–25. One article Dr. Lipe cited showed 60% of patients studied "were initially diagnosed with CIDP and received IVIg therapy," while another article Dr. Lipe cited "says that 85 percent of patients were initially misdiagnosed." *Id.* at 261:3–8. Moreover, once a patient is diagnosed with POEMS, patients are not considered to still suffer from GBS or CIDP. *Id.* at 261:15–17. Dr. Lipe also asserted she was "not aware of any coexisting literature or evidence to suggest that you can have a distinct GBS and a distinct POEMS that are not related." *Id.* at 262:11–13. Dr. Lipe observed petitioner's presentation was not "atypical compared to the other patients with POEMS" whom she treated. *Id.* at 267:24–268:1. Responding to Dr. Latov's and Dr. Parekh's distinction between petitioner's acute onset and the slower progression of POEMS syndrome symptoms, Dr. Lipe asserted "it's accepted that [POEMS] can present acutely[;] . . . the fact that it came on quickly with her symptoms and that she quickly deteriorated is not inconsistent with what I have either personally seen or read." *Id.* at 268:9–13. Ultimately, Dr. Lipe placed the onset of petitioner's POEMS syndrome at November 2013, when she began exhibiting POEMS syndrome symptoms, such as neuropathies, thrombocytosis, pain, and lower extremity edema. *See id.* at 282:12–284:5.

To the extent petitioner challenges the Special Master's finding that petitioner suffered from POEMS, rather than GBS, "the function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner's] injury.'" *Andreu*, 569 F.3d at 1382 (quoting *Knudsen*, 35 F.3d at 549). The Special Master found petitioner did not demonstrate by a preponderance of the evidence that petitioner suffered from GBS, as opposed to POEMS. The Special Master stated, "[a]lthough there is earlier-in-time evidence in the medical records interpreting petitioner's course as GBS, and CIDP thereafter, those records by themselves, viewed in retrospect, suggest that petitioner more likely than not suffered from POEMS syndrome at the outset, rather than GBS or CIDP." *R.S.*, 2019 WL 7631017, at *29. The Special Master first considered the medical records, which showed petitioner continued suffering relapses of symptoms, "despite receiving treatment for presumed GBS and later CIDP." *Id.* The Special Master noted, "[b]ecause GBS/CIDP and POEMS can be confused in their initial presentations, it is not surprising that the treating physicians who first saw petitioner in late 2013 reached different conclusions from those treating her later, in August 2014." *Id.* Moreover, the Special Master observed it was not until petitioner was treated for POEMS that her condition improved. *See id.* In finding the evidence preponderated in favor of a POEMS diagnosis, the Special Master found Dr. Lipe's interpretation of petitioner's medical records more persuasive because Dr. Lipe "based her opinion on a complete review of the record in light of petitioner's entire course," in contrast with petitioner's experts, who "placed too much emphasis on petitioner's earlier-in-time records and treatment responses." *Id.* at 30, 38.

Petitioner lists disagreements with the Special Master's factual findings to argue in favor of a GBS diagnosis. These disagreements concern petitioner's medical history and whether they are properly attributed to GBS and POEMS. Such disagreements, however, seek this Court's reweighing of the evidence, which the Special Master already considered. "[I]t is not . . . the role of this court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence." *Munn*, 970 F.2d at 871. "'[A]rbitrary and capricious' is a highly

deferential standard of review. If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines*, 940 F.2d at 1528; *see also Lampe*, 219 F.3d at 1360 ("The arbitrary and capricious standard of review is difficult for an appellant to satisfy with respect to any issue, but particularly with respect to an issue that turns on the weighing of evidence by the trier of fact."). The Special Master thoroughly reviewed the evidence but was ultimately persuaded by Dr. Lipe's testimony in light of petitioner's medical history.

To the extent petitioner challenges the Special Master's reliance on Dr. Lipe's expert opinion over that of petitioner's experts, "this court accords great deference to a Special Master's determination on the probative value of evidence and the credibility of witnesses." *Pafford v. Sec'y of Dept. of Health & Human Servs.*, 451 F.3d 1352, 1359 (Fed. Cir. 2006). "The fact-finder has broad discretion in determining credibility because [she] saw the witnesses and heard the testimony." *Bradley v. Sec'y of Dept. of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). Indeed, a Special Master's "credibility determinations are 'virtually unreviewable.'" *Hanlon v. Sec'y of Dept. of Health & Human Servs.*, 191 F.3d 1344, 1349 (Fed. Cir. 1999) (quoting *Bradley*, 991 F.2d at 1575)). Moreover, the Special Master provided reasonable explanation why Dr. Lipe's testimony was more persuasive than petitioner's experts; namely, "Dr. Lipe based her opinion on a complete review of the record in light of petitioner's entire course." *R.S.*, 2019 WL 7631017, at *30. Petitioner's experts, on the other hand, "failed to establish a reasonable explanation for petitioner's course in light of her complete medical history" and "were selective in their interpretation of petitioner's multitude of symptoms." *Id.* at *31. Considering petitioner's medical history as a whole is especially important because, as the Special Master noted, "POEMS patients are routinely misdiagnosed with conditions similar to GBS." *Id.* Accordingly, based on Dr. Lipe's testimony as well as the medical records and literature, the Special Master's determination that petitioner suffered from POEMS syndrome was not arbitrary and capricious. *Cedillo v. Sec'y of Dept. of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010) (quoting *Lampe*, 219 F.3d at 1363) ("We 'do not sit to reweigh evidence. [If] the Special Master's conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not arbitrary or capricious.'").

2. Whether the Special Master's Finding that Petitioner Failed to Establish the Flu Vaccine Could Cause GBS and Subsequently POEMS Was Arbitrary or Capricious

Petitioner acknowledges "[t]he possible association between GBS and POEMS [is] less clear, as there is only one report in the medical literature (from Poland) linking the two," but asserts "we are dealing with an exceedingly rare disease for which causation is unknown." Pet'r's Mot. for Review at 3. Petitioner highlights her experts' testimony, which "described a plausible biologic mechanism by which the chronic stimulation of plasma cells from GBS could, in theory, precipitate the formation of a plasma cell neoplasm." *Id.* Petitioner therefore argues "the experts' theory is at least as plausible as any" because "[t]here is no other known etiology for POEMS." *Id.* Respondent asserts, "[o]n review, petitioner acknowledges that the potential relationship between GBS and POEMS syndrome is more speculative" and argues "[p]etitioner does not appear to assert that the special master erred in reaching her conclusion that petitioner

had not established that GBS can cause POEMS syndrome." Resp't's Resp. to Pet'r's Mot. for Review at 18. Instead, respondent contends, petitioner "again improperly requests that this Court reach a different conclusion, based on the same evidence considered by the special master." *Id.*

Reviewing the record, Dr. Parekh relies on the Lindqvist article to establish a purported connection between GBS and POEMS syndrome. *See* Hr'g Tr. at 239:6–8; *see generally* Pet'r's Ex. 59, ECF No. 76-1. The Lindqvist paper is an epidemiological study of monoclonal gammopathy and myeloma patients, which "found that immune or autoimmune conditions increase the risk of plasma cell dyscrasias." Hr'g Tr. at 239:13–15. The paper listed "a number of autoimmune conditions associated with increase in plasma cell dyscrasias," including GBS. *Id.* at 239:15–18. Dr. Parekh posited that "chronic immune stimulation leads to plasma cell dyscrasia," and POEMS is a form of plasma cell dyscrasia. *Id.* at 240:5–7. Dr. Parekh testified the Lindqvist article stands for the proposition that autoimmune conditions are associated with "an increased risk of developing [monoclonal gammopathy of unknown significance ("MGUS")] of almost three-fold." *Id.* at 239:20. Dr. Parekh acknowledged, though, the Lindqvist article does not make an association between GBS and POEMS. *Id.* at 253:5–9.

Dr. Lipe, on the other hand, detailed several issues with the Lindqvist study. First, Dr. Lipe noted the study "started with a group of patients with MGUS," which is an "asymptomatic disease" that "is generally not detected." *Id.* at 273:15–20. Dr. Lipe explained this is problematic because MGUS is typically only found when patients are tested for another underlying condition, and the study did not account for this variable. *See id.* at 273:14–275:7. Dr. Lipe next highlighted that the study found only six out of 26,000 patients studied had concurrent monoclonal gammopathy and GBS, which she asserted "is not something that I think anyone would suggest is evidence of pathogenesis." *Id.* at 275:22–276:6. Dr. Lipe testified she was unaware of any case reports or literature that would support a theory of causation that chronic immune stimulation from GBS/CIDP could cause POEMS. *Id.* at 272:12–17.

Before applying the *Althen* prongs, the Special Master stated "[t]he undersigned's conclusion that petitioner likely did not suffer from GBS at the outset of her illness largely moots petitioner's arguments that the flu vaccine played any role in her development of POEMS syndrome thereafter, given that petitioner's theory requires a finding that she experienced vaccine-induced GBS." *R.S.*, 2019 WL 7631017, at *31. The Special Master recognized "[t]he molecular mimicry theory has been accepted in the Vaccine Program as a reliable explanation for how the flu vaccine can initiate an autoimmune process resulting in GBS." *Id.* at *32. The Special Master reasoned, though, that "[a]part from her inability to show that she more likely than not suffered from GBS at the outset, however, petitioner has also failed to preponderantly establish that chronic inflammation produced secondarily due to GBS can result in plasma cell proliferation let alone instigate POEMS syndrome specifically." *Id.* The Special Master credited petitioner's experts, who "propose[d] that the chronic stimulation of B-cells can cause the body to produce an abundance of plasma cells," but acknowledged "[t]he medical articles offered in support . . . do not support this assertion." *Id.* Moreover, "none of the articles cited by petitioner's experts associate chronic immune stimulation pathologically with the onset of POEMS syndrome." *Id.* Additionally, "the relevant literature offered by experts on both sides which discusses the pathogenesis of POEMS syndrome makes no mention of immune stimulation, whether chronic or acute, as an acceptable biologic mechanism capable of causing

the condition." *Id.* Dr. Latov "even acknowledged at hearing that petitioner's case would be the first reported instance of POEMS syndrome occurring as a direct result of GBS/CIDP via the mechanism posited herein." *R.S.*, 2019 WL 7631017, at *32. For these reasons, the Special Master determined "[s]uch a novel theory, without more persuasive scientific evidence, does not rise to the level of sound and reliable." *Id.* (citing *Boatmon*, 941 F.3d at 1360).

Petitioner's arguments dispute the standard of reliability a medical theory must meet to establish causation in a vaccine case. Under the first *Althen* prong, a petitioner must provide "a medical theory causally connecting the vaccination and the injury." *Althen*, 418 F.3d at 1278. "A petitioner must provide a 'reputable medical or scientific explanation' for its theory." *Boatmon*, 941 F.3d at 1359 (quoting *Knudsen*, 35 F.3d at 548–49). Although this standard "does not require medical or scientific certainty," the theory "must still be 'sound and reliable.'" *Id.* (quoting *Knudsen*, 35 F.3d at 548–49). The Special Master reasoned that even if petitioner met the burden to demonstrate she suffered from GBS at the outset, petitioner "failed to preponderantly establish that chronic inflammation produced secondarily due to GBS can result in plasma cell proliferation let alone instigate POEMS syndrome specifically." *R.S.*, 2019 WL 7631017, at *32. The Special Master considered petitioner's experts' testimony but observed the medical articles they relied upon did not support the theory that the flu vaccine caused GBS, which in turn caused POEMS. *See id.* The Special Master noted, "none of the articles cited by petitioner's experts associate chronic immune stimulation pathologically with the onset of POEMS syndrome." *Id.* Without "sound and reliable" medical or scientific literature supporting the link of causation between petitioner's flu vaccine, GBS, and then POEMS, all that remains is petitioner's experts' testimony. *See Andreu*, 569 F.3d at 1379 ("[A] claimant need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act, [but] where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury."). Dr. Latov, however, "even acknowledged at hearing that petitioner's case would be the first reported instance of POEMS syndrome occurring as a direct result of GBS/CIDP via the mechanism posited herein." *R.S.*, 2019 WL 7631017, at *32.

The Federal Circuit has "consistently rejected theories that the vaccine only 'likely caused' the injury and reiterated that a 'plausible' or 'possible' causal theory does not satisfy the standard." *Boatmon*, 941 F.3d at 1360. Petitioner's expert describes the theory in her motion for review as only a "*plausible* biologic mechanism." Pet'r's Mot. for Review at 3 (emphasis added). The Special Master therefore reasonably determined "[s]uch a novel theory, without more persuasive scientific evidence, does not rise to the level of sound and reliable." *R.S.*, 2019 WL 7631017, at *32. The Court accordingly finds the Special Master's determination that petitioner failed to provide a medical theory of causation linking the flu vaccine, GBS, and subsequent POEMS syndrome is neither arbitrary nor capricious. *Bradley*, 991 F.2d at 1571 ("Because the Claims Court correctly concluded that the special master's decision—that the [petitioner] did not prove by a preponderance of the evidence that [the injuries] were . . . caused by the [vaccine at issue]—was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, we affirm.").

3. The Special Master's Decision was Not Arbitrary and Capricious

Petitioner's addendum to the memorandum to the motion for review lists additional factual disagreements, such as: (1) "I do not believe [petitioner] had monoclonal gammopathy early on;" (2) "50% of patients with GBS manifest pain;" and (3) "she was not readmitted with persistent symptoms but with a distinct third recurrence after prior dramatically favorable response to IVIg." Pet'r's Mot. for Review at 6–8. The Court has considered each point petitioner raises but considers them disagreements with factual assertions throughout the Special Master's decision. The Federal Circuit has instructed this Court to uphold a special master's findings of facts unless they are arbitrary or capricious, but petitioner does not argue any of the factual disagreements are arbitrary or capricious. *See Munn*, 970 F.2d at 870 ("The Claims Court owes [fact] findings and conclusions by the special master great deference—no change may be made absent first a determination that the special master was 'arbitrary and capricious.'"). At best, petitioner's disagreements point to evidence in the record against the Special Master's fact findings, but "it is not . . . the role of this court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence." *Id.* at 871.

"Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims. The statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Master's fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process." *Hodges v. Sec'y of Dept. of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993) (citing *Munn*, 970 F.2d at 870)). "If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines*, 940 F.2d at 1528.

The Court finds nothing arbitrary or capricious in the Special Master's decision. Reviewing the record, preponderant evidence shows petitioner suffered from POEMS from the outset of her injury rather than GBS. Further, petitioner failed to demonstrate through a sound and reliable medical theory that the flu vaccine caused petitioner's GBS and subsequent POEMS. To the extent petitioner can point to evidence showing otherwise, simply identifying opposing evidence does not rise to the level of arbitrary and capricious required to disturb the Special Master's decision. These findings were well supported by the medical records, medical literature, and expert testimony. Accordingly, the Special Master's decision was not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Cedillo v. Sec'y of Dept. of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010) (quoting *Lampe*, 219 F.3d at 1363) ("We 'do not sit to reweigh evidence. [If] the Special Master's conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not arbitrary or capricious.'").

III. Conclusion

For the foregoing reasons, the Court **SUSTAINS** the Special Master's decision because it was not arbitrary, capricious, or not otherwise in accordance with law. The Court therefore **DENIES** petitioner's motion for review. The Clerk of Court is directed to enter judgment for respondent.

IT IS SO ORDERED.

s/ Ryan T. Holte
RYAN T. HOLTE
Judge